NATIONAL INSTITUTES OF HEALTH

Instructions for Reviewing and Processing the HHS-716, Initial Report of Financial Interests in Substantially Affected Organizations for Employees of the National Institutes of Health

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The purpose of this document is to provide detailed guidance in the review and processing of the form HHS-716, Initial Report of Financial Interests in Substantially Affected Organizations (SAO) for Employees of the NIH. The form will be completed and processed in the order noted below. DEC jurisdiction for making the final determination and signing the report is governed by:

- whether SAOs are listed; and
- whether the aggregate value of all reported SAOs is below the applicable *de minimis* set in the regulation (5 CFR 2640 Subpart B).

EMPLOYEE See separate detailed instructions for the employee. This is a summary only.

Part I. **Employee Information.** The employee will complete Part I.

Part II. **Summary of Conflict of Interest Law.** The employee will read this part.

Part III. **Financial Interests in Substantially Affected Organizations (SAOs):** The employee will complete this part and submit the report to the Ethics Office with jurisdiction:

- All NIH Top 5 and OD (except for DECs) employees will submit their reports to the NIH Ethics Office.
- Deputy Ethics Counselors (DECs) submit their reports to the Office of the General Counsel, Ethics Division (OGC/ED).
- All other employees submit their reports to their IC Ethics Office.

ETHICS OFFICE REVIEW

Initial Technical Review, IC Ethics Office Staff (includes NEO Staff for Top 5 Employees)

Staff in the Ethics Office which received the submitted report will conduct an initial review, and either finalize or forward the report as follows.

1. **Compare the HHS-716 to the employee's financial disclosure report.** Confirm that all financial interests reported on the HHS-716 are also reported on the financial disclosure report (SF-278 or OGE-450) applicable to the employee. Confirm that all financial interests in SAOs which are reported on the applicable financial disclosure report are also reported on the HHS-716.

2. **Ethics Office staff will review the HHS-716** and confirm whether each SAO listed meets the definition of an SAO.

   a. If all SAOs reported are listed on the web site, continue with step 3.

   b. If any SAO reported is not listed on the web site, research the company, e.g., via the internet or other means. Forward the information and your evaluation to the NIH Ethics Office (NEO)

for concurrence. The NEO will respond within 2 working days to confirm or deny the determination. Once you receive the NEO determination, continue with the next step.

Example:
General Electric Corporation makes medical imaging equipment. Less than 10% of GE's gross income is derived from medical imaging equipment. Recommend that GE not be treated as an SAO.

c. If the financial interest reported is obviously not an SAO, the IC DEC may make that determination and redact the interest, e.g., a publicly available, diversified mutual fund is reported.

3. **Correct the report as necessary.** Based on the comparison of the HHS-716 to the employee's financial disclosure report and the above step, and with the employee's permission, correct the report for the employee. Those holdings reported which do not meet the definition of SAO will be redacted. Redact the information across the entire line and initial next to the identification letter in the first column on the report form to indicate who corrected the report. In background notes information, document the phone call or maintain the electronic mail giving permission to revise an employee's report. DO NOT attach such information to the form, i.e., do not staple it to the form. Maintain it separately in the file.

a. If, after corrections, no financial interests are reported, treat the HHS-716 as having no SAOs reported and mark the appropriate box and finish processing the report as indicated in Step 4a, below.

b. If financial interests are listed, continue with Step 4b or 4c, as applicable, below.

4. **Identify which DEC has jurisdiction for final determination.**

a. Reports which indicate no holdings in Substantially Affected Organizations (SAOs): These reports do NOT require supervisor review. The IC DEC has jurisdiction and will complete the report as indicated in Step 5 below.

b. Reports which indicate SAO holdings, and <u>both</u> of the following conditions apply:
- » All SAOs included on the report are listed on the NIH Ethics Program SAO web page, or were confirmed as SAOs in the step above; **and**
- » All SAOs included on the report are valued at or below the *de minimis* for that type of holding, AND the aggregate value for the type of holding regarding parties/non-parties is at or below the applicable *de minimis*. See 5 CFR 2640 Subpart B for *de minimis* values. See also the summary on the web site:
  http://ethics.od.nih.gov/topics/deminimis.htm

Examples:
An employee holds stock in 5 publicly traded pharmaceutical companies, each valued at $2500. Each SAO holding is below the $15,000 *de minimis* for securities (stock), AND the aggregate value is less than the $15,000 *de minimis* for matters involving parties. **The IC DEC has jurisdiction; no supervisory review is required.** [2640.202(a)]

An employee holds stock in 3 publicly traded pharmaceutical companies, each valued at $7,000. Each SAO holding is below the $15,000 *de minimis* for securities (stock), but the aggregate value is greater than the $15,000 *de minimis* for matters involving parties The **supervisor must review and the NIH DEC has jurisdiction.** [2640.202(a)]

c. Reports which indicate SAO holdings, other than the examples above (all other reports): These reports require a two-level review, first by the IC Ethics Office staff and then by the supervisor. The IC DEC will complete the initial technical and conflict reviews, obtain supervisor review, and forward the report to the NIH Ethics Office. Skip the next step (Step 5) and continue with the **Initial Conflicts Review, Ethics Office Staff** (the next section).

5. For reports under the jurisdiction of the IC DEC, the IC Ethics Office staff will complete the following steps to review and finalize the report:

a. Complete Part V, as follows:

- » Name of DEC: Self explanatory
- » Contact Information: Self explanatory.
- » Title of DEC: Official position title. DEC is a function of an employee with another official title, such as Executive Officer, Assistant Director, etc.
- » Organization: Enter the full organizational name and address for the DEC.

b. Read the statements carefully and mark the appropriate box(es). The IC DEC will use the following resolution options in Part V, Box 5.

- » **Option 5: Divestiture or Recusal Not Required:** Check this box if the identified holdings pose no conflict and the employee does not have to divest the holding nor recuse him/herself from official particular matters involving the entities listed. **IC DECs will use this box for employee reports containing SAOs with values at or below the *de minimis* levels**.

- » **Option 6: Divestiture or Recusal Not Required:** Check this box if the employee reports no financial interests in SAOs in Part III. **IC DECs will use this box for employee reports containing no SAOs.**

c. Obtain the employee's signature in Part VII. Compliance.

d. Instruct employee to keep a copy, or after receiving the signed Compliance page, copy the full report and return a copy to the employee.

e. Enter the relevant data into the NIH Ethics Management Information System (EMIS).

f. File the original report in the employee's ethics file.

STOP HERE. REVIEW IS COMPLETED FOR REPORTS UNDER IC DEC JURISDICTION

FOR REPORTS UNDER NIH DEC JURISDICTION, CONTINUE WITH THE FOLLOWING PROCEDURE.

Initial Conflicts Review, Ethics Office Staff

For extramural staff and 278/450 filers who are not clinical investigators, skip to Step #3.

1. **Search the NIH Research Protocol database**. See Appendix 1 for detailed instructions.

2. **Clarify whether conflicts exist for the investigators**. Using the results of the above search, work with other DECs to identify all employees who need review by the protocol Principal Investigator.

   a. To reduce the amount of time for the Protocol Principal Investigator (PPI), the DEC for the IC of the PPI will act as the lead DEC. The lead DEC will collate the list of SAOs from the investigators across all ICs before contacting the PPI to inquire about potential conflicts for the SAOs in question. Each IC DEC is responsible for sharing that information in a timely manner with the PPI's DEC. Information to be shared includes the following:
      List of SAOs held, by name of SAO only (no employee name associated with an SAO)

      For example, if the PPI is from the Clinical Center, the Clinical Center DEC will gather information from the other DECs regarding which SAOs are held by the investigators from other ICs who serve on the protocol. If other DECs obtain information before being contacted by the Clinical Center DEC, they should forward the information to the Clinical Center DEC immediately.

   b. The PPI's DEC will contact the PPI, and send a list of SAOs held by all investigators on the protocol. The PPI will indicate by each SAO listed whether it s a party to the matter, whether it is an entity not party to the protocol but which could be affected by the protocol (non-party), or whether the protocol would have no effect on the entity.

   c. Ethics staff will then compare the annotated list of outside entities returned by the PPI with the employees' reports and determine if a real or apparent conflict of interest exists by analyzing the value(s) of the SAO(s) listed on the employee's report against the applicable *de minimis* for that type of holding.

   d. Document the results of the comparison and DEC determination on page 12, Additional Space, as shown in the following examples:

      Examples:
      Employee holds Merck stock, and is personally and substantially involved in a research protocol entitled xxxx,, which can directly and predictably affect Merck. Conflict needs resolution.

      Employee holds Merck stock, and is personally and substantially involved in a research protocol entitled xxxx, which can directly and predictably affect a competitor, Pfizer, which makes a similar product as that being used in the protocol. Conflict needs resolution.

      Employee holds stock in SAOs, none of which can be affected by official participation in a research protocol entitled xxxx. No conflict for this official responsibility.

   e. Sign and date below the notes on page 12.

3. **Prepare the report for supervisor review.** This process assumes that there are some SAOs listed which require supervisor review.

   a. Copy pages 3 and 4 of the form, and the Additional Space page (page 12) if the employee or DEC used this page, or additional pages attached by the employee or DEC. Use the copy to redact information on ownership and value.

   b. For each SAO listed, redact the value (actual dollar amount). Use "White Out" or "Redaction Tape" to cover the amount.

   c. Copy the redacted pages and produce a copy for the supervisor, to include:
      - » Page 1, the employee information page
      - » Pages 2 and 3, Summary of Conflict of Interest Law
      - » Pages 4 and 5, the Employee Financial Interests pages
      - » Pages 6 and 7, the Supervisor Review pages
      - » Page 12.

4. **Staple the pages of the redacted copy together and send the report to the Supervisor.** Prepare a cover note giving the due date back to you. If a particular supervisor has a large number of reports to review, ask to have the reports returned to you in batches rather than all at once when the supervisor finishes reviewing them.

5. **Keep track of reports and remind supervisors** as needed to ensure timely review and return of reports.

SUPERVISOR REVIEW

Reports from non-senior NIH employees which list SAO holdings will be forwarded to the supervisor indicated in Part I, Box 10, for a conflict of financial interest review. Definitions and examples of what constitute a conflict of interest are provided in the slides from the Supervisor Training (see Appendix 2).

The employee will have already submitted his/her completed HHS-716 to the appropriate Ethics Office, where initial technical and conflicts review have been performed. The supervisor will:

1. **Read the information that the employee is required to read on pages 2 and 3**.

2. **Examine the employee's current official duties** and identify whether the employee has official responsibilities of significance to the resolution of Government matters that affect any SAO. Keep in mind that the employee's official responsibilities might directly or indirectly affect an outside organization. Note the affected organizations on the report, e.g., highlight the holdings for easy reference.

   - » **Directly affected** outside entities may include those organizations with which the employee has some official interaction, such as a partner in an official collaborative endeavor. These entities may be a 'party' to a particular matter, such as a CRADA partner.

   - » **Indirectly affected** outside entities includes those organizations which could be affected by the results of a matter, even though the entity may not be involved in the matter. These entities would be considered 'non-parties' since they are not part of the particular matter, but could be affected by the outcome. For example, the outcome of a drug trial can affect not only the maker of the drug being tested, but also the maker of a competing drug.

3. **Compare those affected outside organizations** with the financial interests reported on the employee's HHS-716, in Part III (pages 4 and 5).

4. **Read DEC comments on page 12, if any.**

5. **Using information gained in the above steps, complete Part IV of the HHS-716:** (pages 6-7)

   a. **Box 1. Description of Potential Conflicts.** Read the instructions and provide the requested evaluation. You are to describe the potential conflicts. Use the Additional Space on page 12 as needed. Clearly identify your comments as Part IV, #1.

      Examples:
      Employee has a financial interest in Merck, which produces a competing drug to one being used in a protocol on which he works. Employee is in charge of data collection on the protocol, which is personal and substantial participation.

      Employee is the PI on a CRADA, has a financial interest in Merck, and the CRADA uses materials from Pfizer, which makes similar materials. As PI, employee makes or oversees all decisions regarding the CRADA.

   b. **Box 2. Resolution of Potential Conflicts:** Read the instructions and provide the requested information. This section is for the supervisor to indicate any concerns and to share the evaluation with the DEC regarding resolution of any identified potential conflicts. Respond to all three issues as directed. Use the Additional Space on page 12 as needed. Identify your comments as Part IV, #2a, #2b, or #2c, as appropriate.

      » **Question a. Reassignment of Work to Another Individual:** Read the instructions and indicate whether the work can be reassigned and why.

         Examples:
         Employee is a clinical nurse whose function on several protocols is to collect data. The employee's financial interest in Merck can be affected by one protocol, entitled xxx. Since several clinical nurses function as data collectors across several protocols, this employee can be reassigned to another protocol without harming the integrity of the protocol nor negatively affecting the employee's workload or that of other data collection staff.

         Employee is PI on a CRADA entitled XX with Pfizer, because of his expertise in that specific area. The outcome of the CRADA can reasonably be expected to affect his own financial interests in Merck. The PI responsibility cannot be reassigned without harming the expected contribution of the protocol.

      » **Question b. Nature of Work Assignments.** Read the instructions and indicate whether the affected work is a critical portion of the employee's work.

         Examples:
         Handling data collection is a major portion of the employee's work, but it is not critical that the employee do so on this particular protocol.

         The employee's work as PI is critical to the CRADA, and central to the employee's research work.

» **Question c. Material Impairment of Ability to Perform Duties of Position:** Read the instructions and indicate whether the employee's ability to perform official work would be significantly affected if the employee were removed from performing the official work which affects the outside organization.

Examples:
There would be no significant impairment for the protocol or the employee if the employee is recused from data collection on the particular protocol. Workloads can be realigned to permit employee to work on other protocols.

There would be substantial impairment of the employee's ability to perform his official duties if he were recused from the CRADA.

6. **Box 3. Comments:** See the instructions. You may also direct the DEC to your comments on Page 12, Additional Space.

7. **Sign and date the report**. Return it to the Ethics Office that sent it to you. Do NOT keep a copy of the report.

DEPUTY ETHICS COUNSELOR DETERMINATION

The Ethics Office staff and DEC have already performed the initial technical and conflicts review and sent a redacted copy of the report to the supervisor. The IC DEC reviews the supervisor's evaluations and comments, and indicates agree or disagree, and forwards the report to the NIH Ethics Office (NEO). DEC jurisdiction is governed by:

- whether SAOs are listed;
- whether those reported SAOs are listed on the NIH Ethics Program web site; and
- whether the value of the reported SAO is below the *de minimis* set in the regulation (5 CFR 2640 Subpart B).

IC DEC Review

1. **Receive Report from Supervisor.** Review the supervisor's comments. Replace the Supervisor pages (6, 7) (and add the Additional Space, page 12, if the supervisor used page 12) into the original report so that the final report contains original signatures of the employee and the supervisor. Save the redacted pages separate from the final form to document what was sent to the Supervisor.

2. **IC DEC Indicate Concur or Nonconcur and Sign:** Sign and date at the bottom of page 7, below the Supervisor's signature, indicating that you read and agree or disagree with the evaluation. Add comments or other suggestions for resolutions on page 12, Additional Space. Clearly label your comments "IC DEC Comments". You may also use an additional blank page for comments. Indicate "See Comments" by your signature. Make a copy of the entire report for your files.

3. **Forward to NIH Ethics Office:** Forward the full report with original signatures to the NIH Ethics Office (Bldg 2, Room BE-15A, MSC 0201).

NEO Review and NIH DEC Determination

1. **Receive Report from the IC DEC**.

2. **Review All Comments and Evaluations:** On behalf of the NIH DEC, the NIH Ethics Office (NEO) staff will review all comments and evaluations, and prepare the HHS-716 for final review and determination by the NIH DEC.

    a. Name of DEC: Self explanatory

    b. Contact Information: Self explanatory.

    c. Title of DEC: Official position title. DEC is a function of an employee with another official title, such as Executive Officer, Assistant Director, etc.

    d. Organization: Enter the full organizational name and address for the NIH DEC.

3. **NIH Deputy Ethics Counselor Determination:** The NIH DEC will review the evaluations and comments, and make the final determination by marking the appropriate boxes.

    a. **Total Divestiture of Specified Interests:** Check this box to instruct the employee to divest the full amount of certain types of holdings as identified in the boxes below this section. Use the identification letters associated with each listed interest.

    b. **Partial Divestiture:** Check this box to instruct the employee to divest down to a certain level (i.e., the *de minimis*). Indicate the letter identification for each holding that must be partially divested.

    c. **Partial Divestiture by Senior NIH Employees:** Check this box and indicate the letter identification of each prohibited financial interest which the NIH Senior Employee must divest down to the *de minimis* level.

    d. **Recusal with respect to Particular Matters:** Check this box and indicate the letter identification of each SAO which the employee may retain, but the employee must be recused from all official particular matters involving that specific SAO.

    e. **Divestiture or Recusal Not Required:** Check this box if the identified holdings pose no conflict and the employee does not have to divest the holding nor recuse him/herself from official particular matters involving the entities listed.

    f. **Divestiture or Recusal Not Required:** Check this box if the employee reports no financial interests in SAOs in Part III.

    g. **Other Disposition:** Check this box if some other resolution is being used, and describe that resolution on the blank page 12 Clearly identify the comments as “Part V, Other Disposition.” For example, the NIH DEC may recommend a waiver to resolve an identified conflict.

4. **Sign and date the report; return it to NEO staff to finalize.**

NIH ETHICS OFFICE (NEO) FINALIZES REPORT

These instructions also apply to the Office of the General Counsel, Ethics Division, which handles all financial disclosure reports for Deputy Ethics Counselors.

1. Review NIH DEC Determinations:

a. If there are no required employee actions, continue with step 7.

b. If the employee must divest or take other remedial action, retain the original and return a copy to the employee with instructions to review the DEC Determination in Part V, and to follow the employee instructions for Parts VI and VII. Give a deadline of 2 weeks to request a CD. Send a copy to the employee's IC Ethics Office for information.

2. Periodically follow up with employee to check on progress, e.g., weekly. If the employee wishes to request a Certificate of Divestiture (CD), s/he must notify the DEC within 2 weeks of the DEC signature in Part V by returning the original form with the CD request, as outlined in Part VI, box 2.

3. Receive Signed Part VI. Certificate of Divestiture from the Employee: Confirm that the employee checked the appropriate box, signed the report, and provided the additional information as needed. Insert the signed page into the original report and discard the blank page.

» If the employee requests a CD, continue with the next step.
» If the employee does NOT request a CD, continue with step 5.

4. Employee Requests a CD:

a. Immediately initiate the CD request package with input from the employee and the Office of the General Counsel, Ethics Division (OGC/ED). Submit the request package to OGC/ED as soon as it is complete.

b. When the CD approval/disapproval document is received, forward it to the employee with a copy of page 11, Part VII. Compliance.

c. Follow up with employee with reminder that the deadline for divestiture is January 30, 2006.

d. If other actions (e.g., recusal) are also required, remind the employee of the need to quickly comply with those requirements.

e. Continue with step 6.

5. Employee Does Not Request a CD:

» If the employee does not request a CD and has NOT submitted a signed Part VII. Compliance, add the signed Part VI. Certificate of Divestiture to the original report and discard the blank page. Remind the employee of the need to divest within 90 days, and to comply with the other remedial requirements as quickly as possible. Continue with the next step.

» If the employee does not need to divest and submits a signed Part VII. Compliance, continue to step 6.

6. **Receive Signed Part VII. Compliance From the Employee:** Upon receipt of the signed page, insert the signed Part VII (page 10) into the original report form and discard the blank page. Confirm that your copy has all the original pages.

7. **Enter data in EMIS.**

8. **Copy the complete report and distribute as directed below:**

   a. **Non-senior employees:** The employees' ethics files are maintained by the IC Ethics Office. Send the original report to the IC Ethics Office. The IC Ethics Office will file the original in the employee's ethics file and send a copy of the full report to the employee. There is no need to keep a copy in NEO.

   b. **Senior (Top 5) employees:** The employees' ethics files are maintained in the NEO. Make two copies and forward them to the IC Ethics Office, who will file one copy in the employee's ethics file there, and send a copy to the employee.

   c. **DECs:** The original is filed in the employee's financial disclosure file in OGC Ethics Division. Make two copies, one for the employee and one for the appropriate ethics office (NEO for Top 5; IC Ethics Office for others). OGC/ED staff will enter data into EMIS.

NOTE TO ALL ETHICS STAFF:

When filing the final HHS-716, include ONLY the original pages in the form. All copies used to obtain supervisor review, all electronic messages, all documentation of phone calls, and other information used to conduct the review are NOT part of the form and must **not** be stapled or otherwise attached to the final HHS-716. Such collateral information may be saved in the employee's ethics file, appropriately labeled.

To attach any additional information to the form makes that additional information legally part of the form, and subject to release if the form is released.

Appendix 1, NIH Protocol Query System (Active Intramural Research Protocols)

The content for the Protocol Query System (PQS) application is a subset of data from the database Protrak, maintained by the Office of Protocol Services (OPS), in the NIH Clinical Center. The site is updated nightly reflecting changes in the protocol actions submitted and approved by the Intramural Institutional Review Board (IRB) and processed by the OPS. The PQS permits ethics staff to identify any official participation in protocols which involve outside entities. The application is available on the NIH intranet (accessible only from NIH computers) at: http://pqs.cc.nih.gov

The application provides 3 search options:

1. Institute of the Principal Investigator
2. Investigator last name
3. Protocol number

Search Instructions

1. Open the web site and logon.

2. Select the type of search desired from the drop down box.

3. Enter the search criteria:

   a. To retrieve by the IC of the Principal Investigator (PI), enter the IC's PQS abbreviation, i.e.,:

CC	CC	NIAAA	AA	NIDCR	DC
NCI	C	NIAID	I	NIEHS	E
NHGRI	HG	NIAMS	AR	NIMH	M
NEI	EI	NICHD	CH	NINDS	N
NHLBI	H	NIDCD	DC	NINR	NR
NIA	AI	NIDDK	DK	NCCAM	AT

   b. To retrieve by PI last name, enter the last name, e.g., Smith.

   c. To retrieve by specific protocol, enter the full protocol number, e.g, 99-C-0058. The sections of the entire protocol number are defined as follows:
      - The first two digits of the protocol number represent the fiscal year during which the protocol was implemented.
      - The next one/two letter(s) represent the IC financially responsible for the protocol.
      - The remaining four digits provide a sequential number assigned to the protocol by the Office of Protocol Services (OPS) in the Clinical Center.

      Protocols in which patients are not seen at the Clinical Center will have either the fiscal year preceded by the letters "OH" (i.e., OH99-C-0083), or the letter "N" preceding the sequential number of the protocol number (i.e., 99-C-N083).

   d. To retrieve IC protocols by year, enter just year and IC, e.g., 05-CC.

4. Click on "Search."

Sort Order of Results

The results for each search will be ordered according to:

- Search by IC: results are sorted by protocol number, from newest to oldest.

- Search by Investigator: results are sorted alphabetically by investigators' last name, first name, and within by protocol number from newest to oldest.

Content of Results

Results of the search include the following information:

Protocol # NIH Intramural protocol number

Title Official title of the study

IRB The Institutional body responsible for the regulatory oversight of the protocol.

Investigator List

Contains the investigators associated with the protocol, identifying:

- Name
- Role: Association to the protocol
  - » PI: Principal Investigator
  - » AI: Associate Investigator
  - » MAI: Medically Advisory Investigator
  - » RC: Research Contact
- Start Date: Reflects the date on which the investigator was first identified in one of the four roles. Dates were retrospectively entered for investigators serving as PIs, using the earliest date in which s/he started. The date 11/1/05, point of implementation, is reflective as the start date for Investigators who are not PIs. The actual ate an investigator assumed responsibility in one of the 4 roles will be used from this point forward for any new investigators.
- IND/IDE List: Identifies investigational drugs/devices identified by the PI on the initial/continuing review protocol application.
- Commercial Entities: identifies commercial or other entities providing the IND/IDE as identified by the PI on the initial or continuing review protocol application.
- Precis: The scientific summary of the protocol.

Assistance

Questions may be addressed to and assistance obtained from:

Kim Jarema Office of Protocol Services 301-435-2401 kjarema@cc.nih.gov

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Appendix 2, Slides From Supervisor Training For Reviewing the Form HHS-716

Slides from the Supervisor Training for Reviewing the Form HHS-716, are available electronically on the NIH Ethics Program web site, from the Home Page: http://ethics.od.nih.gov/train/sup-train.htm

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